

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
SAVANNAH DIVISION

FILED
U.S. DISTRICT COURT
SAVANNAH DIV.

2007 OCT 17 AM 9:06

UNITED STATES

v.

405CR059

MARTIN J. BRADLEY, III, et al.

CLERK

SD. DIST. OF GA.

ORDER

This Order assumes familiarity with the Court's prior Order on the "PDMA-disposal"¹ issue raised in motions # 875 and # 946, and analyzed in this Court's Orders docketed at # 903 and # 933. Briefly, the Court appointed a Receiver and a Monitor in this complex criminal RICO case to collect forfeiture and, later, sentencing obligations from jury-convicted

defendants Martin J. Bradley, Jr., Martin J. Bradley, III, Albert Tellechea and Bio-Med Plus, Inc. (Bio-Med). In liquidating Bio-Med, the Receiver moved the Court for an Order granting her leave to dispose of Bio-Med's "non-pedigreed" and expired pharmaceutical inventory. Doc. # 875. The Court deferred ruling in light of Bio-Med Shareholders' (Maria and Martin J. Bradley, III's) opposition response brief, doc. # 891, which the Court found persuasive enough to invite a Reply brief from the Receiver. Doc. # 892. The Receiver twice replied. Doc. ## 893, 897.

¹ Under the Prescription Drug Marketing Act (PDMA),

[e]ach person who is engaged in the wholesale distribution of a drug subject to subsection (b) of this section and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug ... provide to the person who receives the drug a statement ... identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

21 U.S.C. § 353(e)(1)(A) (emphasis added). "The PDMA's purpose is to protect the American consumer from tainted pharmaceuticals. The pedigree requirement was created to show where wholesale distributors were obtaining their drugs." *RxUSA Wholesale, Inc. v. Dep't of Health & Human Servs.*, 467 F.Supp.2d 285, 290 (E.D.N.Y. 2006). The *RxUSA* court addressed a constitutional issue and enjoined an implementing regulation, *id.* at 296, but essentially said that for public safety reasons everyone, whether an authorized or an unauthorized distributor (like Bio-Med), must prove a drug's pedigree at least as far back to the authorized distributor through which the drug passed. Doc. # 903 at 7 (emphasis added).

The Court then rejected many of the Shareholders' arguments, but found some compelling enough to deny the Receiver's motion without prejudice. Doc. # 903. Joined by the Government, doc. # 915, the Receiver renewed her motion to destroy the non-pedigreed drugs, doc. # 913, which Shareholder Maria Bradley continued to oppose. Doc. # 926.

As of the Court's last Order, doc. # 933, the Receiver represented that what was left of Bio-Med (she had sold its other assets on 4/9/07, doc. # 913 at 2 n. 1) were nonconforming ("non-pedigree") pharmaceutical drugs. Doc. # 875 at 2. She insisted that those drugs, which were otherwise valued at \$653,123, must be destroyed pursuant to the PDMA. *Id.* at 3.

The Receiver would not, she explained, be able to represent to third-party buyers that this particular portion of Bio-Med's inventory would meet the "pedigree" requirements -- because she could not establish for the drugs a "transactional history" back to an authorized distributor, if not

a manufacturer. Doc. # 875 at 2-3 ¶ 7; *see also* doc. # 926, exh. A at 24-25. She therefore had to destroy the drugs at a cost of over \$2,000. Doc. # 875 at 3. She thus again sought the Court's approval to proceed. *Id.* at 4. And once again, the Shareholders opposed. Doc. # 891.

The Court then sifted each of the Shareholders' arguments before also rejecting them, but invited a reconsideration motion

showing (a) how *anyone* might legally sell these drugs (the Receiver essentially has sold Bio-Med and thus lacks personnel, doc. # 913 at 2 n. 1, but there is no suggestion that she could not hire temporary help), and thus (b) how the post-RxUSA pedigree requirement can be met.

Doc. # 933 at 9. Meanwhile, the Court emphasized that it did


not reach this result lightly. \$653,123 is a huge amount of product to be destroyed, especially in a world where so many go without. Congress, however, has erred on the side of safety. Still, the Court will entertain a motion for stay pending appeal, as the burden on the Receiver appears minimal (she is not, for example, seeking to *preserve* an asset; rather, she is seeking to *destroy* an asset, and spend over \$2,000 in the process).

Id. at 9-10. Finally, the Court assured the Bradley Shareholders that if they filed a reconsideration or stay motion within that time, disposal shall not proceed during that motion's pendency. *Id.* at 10. Maria did. Doc. # 946 at 3 (citing a pressing briefing schedule for the main appeal, she sought a "stay, pending the disposition of all appeals, the destruction of the subject inventory"); *see also* doc. # 952 (Bradley, III joins her); doc. # 958 (Receiver

insisting that "a stay of the destruction of the non-pedigree inventory pending appeal would be pointless").

The Monitor's 9/27/07 Report² at 8 and 11 notes the Receiver's expectation of a legal opinion, from the King and Spalding law firm, on the pedigree of the suspect inventory. She expected an opinion "before the end of [9/07,] after which she will decide whether to sell or request permission to destroy this inventory...." *Id.* at 8. The Court directs the Receiver to provide it with updating information on that score (she may file a supplemental brief or motion). Any party with standing may respond within 10 days thereafter. The stay motion, doc. # 946, meanwhile, is **GRANTED**.

This 17 day of October, 2007.


B. AVANT EDENFIELD, JUDGE
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA

² This should be filed in the record. *See* doc. # 1028. The Monitor is directed to file all of its reports in the record, rather than send them directly to the undersigned.